

1. Receipt is acknowledged of a preliminary amendment and a prior art information disclosure statement filed April 26, 2008 for this application which is a 371 of PCT/US04/34755 filed 10/21/2004 which claims benefit to Provisional Application 60/514694 filed 10/27/2003.

2. Claims 1-30 are now pending in this application.

Claim 31 has been cancelled.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim(s) 1 [and dependent claims 29-30] are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The claim lacks critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure since the claim lacks any process step(s) for the preparation of the kinetic resolution absent the conditions which requires conditions for "enzyme-catalyzed dynamic kinetic resolution by equilibrating the two chiral centers of (+/-)-(2R\*,3R\*)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Morgan et al U.S. 6,274,579; Morgan et al 6,391,875; Broom et al U.S. 6,855,820; Asher et al U.S. 6,998,400 or Musso U.S. 7,098,206.

Each one of the above references teaches the claimed (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol and the treating of a disorder with the claimed product.

**Morgan et al 6,391,875 or 6,274,579 recites:**

Disclosed is the compound (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol and pharmaceutically acceptable salts and solvates thereof, pharmaceutical compositions comprising them; also disclosed is a method of treating depression, attention deficit hyperactivity disorder (ADHD), obesity, migraine, pain, sexual dysfunction, Parkinson's disease, Alzheimer's disease, or addiction to cocaine or nicotine-containing (especially tobacco) products using such compound, salts, solvates or compositions.

**Asher et al teaches:** Disclosed is the compound (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol and pharmaceutically acceptable salts and solvates thereof, pharmaceutical compositions comprising them, and processes for their preparation; also disclosed is a method of treating depression, attention deficit hyperactivity disorder (ADHD), obesity, migraine, pain, sexual dysfunction, Parkinson's

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disease, Alzheimer's disease, addiction to cocaine or tobacco products, seasonal affective disorder, chronic fatigue, narcolepsy or cognitive impairment using such compound, salts, solvates or compositions.

**Broom et al teaches:**

Disclosed is the compound (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol and pharmaceutically acceptable salts and solvates thereof, methods for preparing them, pharmaceutical compositions comprising them, and processes for their preparation; also disclosed is a method of treating depression, attention deficit hyperactivity disorder (ADHD), obesity, migraine, sexual dysfunction, Parkinson's disease, Alzheimer's disease, or addiction to cocaine or nicotine-containing (especially tobacco) products using such compound, salts, solvates or compositions.

**Musso** teaches the following:\_\_\_\_\_ (26):

The absolute configuration of (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol was determined by the following x-ray crystallographic method. Crystal

And recites:

1. A method of treating depression in a mammal comprising the administration to said mammal of an effective amount of (+)-(2S,3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol or pharmaceutically acceptable salts and solvates thereof.

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5. Claims 2-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HERBERT J. LILLING whose telephone number is 571-272-0918. The examiner can normally be reached on WORK AT HOME MAXIFLEX.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JON WEBER can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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June 01, 2008

/HERBERT J LILLING/  
Primary Examiner Art Unit 1657